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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,983	10/02/2003	Robin A. Felder	FELDER 3.9-001 CONT DIV	9056

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/677,983	FELDER ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-38 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to an isolated nucleic acid encoding a mutant GRK4 protein and oligonucleotides which hybridize to a GRK4 gene, classified in class 536, subclass 23.5 and class 536, subclass 24.33.

II. Claims 4-8, drawn to a method of identifying individuals predisposed to essential hypertension by protein analysis, classified in class 530, subclass 350.

III. Claims 9-13 and 22-24, drawn to a reconstituted system for assaying GRK activity, and a method of identifying putative anti-hypertensive agents by detecting GRK4 activity, classified in class 435, subclass 4.

IV. Claim 14, 25, and 26, drawn to a complex and a method of identifying putative anti-hypertensive agents by protein analysis, classified in class 436, subclass 173.

V. Claims 15-17, drawn to a human proximal tubular cell, classified in class 435, subclass 369.

VI. Claims 18-21 and 28, drawn to (i) a transgenic animal comprising a transgene encoding a GRK4 protein and (ii) a method of identifying putative anti-hypertensive agents using a transgenic animal, classified in class 800, subclass 13.

VII. Claim 27, drawn to a method of identifying putative anti-hypertensive agents in cell culture, classified in 435, subclass 325.

VIII. Claim 29 and 34, drawn to a method of increasing natriuresis using a drug that interacts with the GRK4 protein, classified in class 514, subclass 1.

IX. Claims 30, 31, 35, and 36 drawn to a method of increasing natriuresis using a drug that changes expression of GRK4 in kidney cells, wherein said drug is antisense RNA, and an antisense oligonucleotide, classified in class, 536, subclass 24.5.

X. Claims 32 and 38, drawn to a method of increasing natriuresis using a drug that changes expression of GRK4 in kidney cells, wherein said drug is a ribozyme, and a ribozyme that cleaves GRK4 mRNA, classified in class 536, subclass 23.5.

XI. Claims 33 and 37, drawn to a method of increasing natriuresis using a drug comprising a dominant negative mutant DNA molecule, and an oligonucleotide which is a dominant negative mutant DNA molecule, classified in class 514, subclass 44.

In the groupings listed above, products and their respective processes of using have been grouped together.

The inventions are distinct, each from the other because of the following reasons:

Invention I and each of inventions II-XI are patentably distinct, each from the other, because the inventions are drawn to distinct compositions and methods that are not used together. The composition of the invention of Group I is not used in the methods of the inventions of Groups II-XI. Thus, the composition of the invention of Group I is patentably distinct from each of the inventions of Groups II-XI.

Invention II and each of inventions III-XI are patentably distinct, each from the other, because the inventions are drawn to distinct methods that require different starting materials, different modes of operation, and produce different effects. The compositions of the inventions of Groups III-XI are not required for and cannot be used in the method of the invention of Group II. As noted above, products and

their respective processes of using have already been grouped together. Thus, the method of the invention of Group II is patentably distinct from each of the inventions of Groups III-XI.

Invention III and each of inventions IV-XI are patentably distinct, each from the other, because the inventions are drawn to distinct methods that require different starting materials, different modes of operation, and produce different effects. Furthermore, the composition of the invention of Group III is not required for and cannot be used in the methods of the inventions of Groups IV-XI. As noted above, products and their respective processes of using have already been grouped together. Thus, the method and composition of the invention of Group III is patentably distinct from each of the inventions of Groups IV-XI.

Invention IV and each of inventions V-XI are patentably distinct, each from the other, because the inventions are drawn to distinct methods that require different starting materials, different modes of operation, and produce different effects. Furthermore, the composition of the invention of Group IV is not required for and cannot be used in the methods of the inventions of Groups V-XI. As noted above, products and their respective processes of using have already been grouped together. Thus, the method and composition of the invention of Group IV is patentably distinct from each of the inventions of Groups V-XI.

Invention V and each of inventions VI-XI are patentably distinct, each from the other, because the inventions are drawn to distinct compositions and methods that are not used together. The composition of the invention of Group V (i.e., the human proximal tubular cell) is not used in the methods of the inventions of Groups VI-XI. As noted above, products and their respective processes of using have already been grouped together. Thus, the composition of the invention of Group V is patentably distinct from each of the inventions of Groups VI-XI.

Invention VI and each of inventions VII-XI are patentably distinct, each from the other, because the inventions are drawn to distinct methods that require different starting materials, different modes of

operation, and produce different effects. Furthermore, the composition of the invention of Group VI (i.e., the transgenic animal) is not required for and cannot be used in the methods of the inventions of Groups VII-XI. As noted above, products and their respective processes of using have already been grouped together. Thus, the method and composition of the invention of Group VI is patentably distinct from each of the inventions of Groups VII-XI.

Invention VII and each of inventions VIII-XI are patentably distinct, each from the other, because the inventions are drawn to distinct methods that require different starting materials, different modes of operation, and produce different effects. The compositions of the inventions of Groups VIII-XI are not required for and cannot be used in the method of the invention of Group VII. As noted above, products and their respective processes of using have already been grouped together. Thus, the method of the invention of Group VII is patentably distinct from each of the inventions of Groups VIII-XI.

Invention VIII and each of inventions IX-XI are patentably distinct, each from the other, because the inventions are drawn to distinct methods that require different starting materials, different modes of operation, and produce different effects. The compositions of the inventions of Groups IX-XI are not required for and cannot be used in the method of the invention of Group VIII. As noted above, products and their respective processes of using have already been grouped together. Thus, the method of the invention of Group VIII is patentably distinct from each of the inventions of Groups IX-XI.

Invention IX and each of inventions X and XI are patentably distinct, each from the other, because the inventions are drawn to distinct methods that require different starting materials, different modes of operation, and produce different effects. Furthermore, the compositions of the invention of Group IX (i.e., the antisense RNA and antisense oligonucleotide) is not required for and cannot be used in the methods of the inventions of Groups X and XI. As noted above, products and their respective processes of using have already been grouped together. Thus, the method and composition of the invention of Group IX is patentably distinct from each of the inventions of Groups X and XI.

Inventions X and XI are patentably distinct, one from the other, because the inventions are drawn to distinct methods that require different starting materials, different modes of operation, and produce different effects. Furthermore, the composition of the invention of Group X (i.e., the ribozyme) is not required for and cannot be used in the methods of the inventions of Group XI. As noted above, products and their respective processes of using have already been grouped together. Thus, the method and composition of the invention of Group X is patentably distinct from the inventions of Group XI.

With regard to burden, MPEP § 808.02 states that, to establish that there would be a serious burden on the examiner if restriction is not required,

> "the examiner must show by appropriate explanation one of the following:
> (A) **Separate classification thereof:** This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification." (emphasis original)

Thus, to establish that a serious burden exists, it is sufficient to show separate classification of the inventions. The instant inventions have separate classifications and require separate search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Thursday from 10:00 AM to 8:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER